

EXHIBIT 7

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April 15, 2024

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OF:**

APPLICATION NUMBER: 16/915,558

FILING DATE: June 29, 2020

PATENT NUMBER: 11395889

ISSUE DATE: July 26, 2022



Certified by

Kathi

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| In re application of: | : | | |
| Declan Walsh <i>et al.</i> | : | | |
| | : | | |
| Conf. No.: 3133 | : | Group Art Unit: | 2876 |
| | : | | |
| Appln. No.: 16/915,558 | : | Examiner: | Daniel A. Hess |
| | : | | |
| Filing Date: June 29, 2020 | : | Attorney Docket No.: | 026723-5043-US20 |
| | : | | |
| Title: | : | | |
| Dose Counter for Inhaler Having An Anti-Reverse Rotation Actuator | : | | |

AMENDMENT UNDER 37 C.F.R. § 1.111

The following Amendment is submitted in response to the Office Action dated April 21, 2021.

Except for issue fees payable under 37 C.F.R. § 1.18, the Director is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. **50-0310** (Billing No. 026723-5043-US20). This paragraph is intended to be a Constructive Petition For Extension Of Time in accordance with 37 C.F.R. § 1.136(a)(3).

AMENDMENTS TO THE CLAIMS begin on page 2 of this paper; and

REMARKS/ARGUMENTS begin on page 4 of this paper.

Please amend the above-identified application as follows:

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LISTING OF THE CLAIMS

The following listing of the claims will replace all prior versions and listings of claims in the application.

1-22. (Cancelled)

23. (Currently Amended) An incremental dose counter for a metered dose inhaler having a body arranged to retain a canister for movement of the canister relative thereto, the incremental dose counter having a main body, an actuator arranged to be driven and to drive an incremental output member in a count direction in response to canister motion, the actuator being configured to restrict motion of the output member in a direction opposite to the count direction, such that the actuator acts as an anti-back drive member when the metered dose inhaler is not being used for inhalation.

24. (Previously Presented) The incremental dose counter as claimed in claim 23 in which the output member comprises a ratchet wheel.

25. (Previously Presented) The incremental dose counter as claimed in claim 24 in which the actuator comprises a pawl and in which the ratchet wheel and pawl are arranged to permit only one way ratcheting motion of the ratchet wheel relative to the pawl.

26. (Previously Presented) The incremental dose counter as claimed in claim 25 further including an anti-back drive member fixed to the main body.

27. (Previously Presented) The incremental dose counter as claimed in claim 26 in which, when in a rest position of the dose counter, the ratchet wheel is capable of adopting a configuration in which a back surface of one tooth thereof engages the anti-back drive member and the pawl is spaced from an adjacent back surface of another tooth of the ratchet wheel without positive drive/blocking engagement between the pawl and ratchet wheel.

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28. (Previously Presented) A dose counter as claimed in claim 23 wherein an incremental counting system is arranged to move a counter display incrementally in a first direction from a first station to a second station in response to actuation input, wherein a regulator is provided which is arranged to act upon the counter display at the first station to regulate motion of the counter display at the first station to incremental movements.

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REMARKS

1. Claims 23-28 are currently pending in the application, as amended. Claim 23 has been amended. Support for the amendments can be found throughout the originally filed specification and figures, at least at paragraph [0152] and FIG. 10B.

Claim Rejections – 35 U.S.C. § 103

2. Claims 23-28 stand rejected under pre-AIA 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 6,446,627 to Bowman *et al.* (hereinafter “Bowman”). Applicant respectfully traverses this rejection for the reasons set forth below.

Amended claim 23 recites the following, with emphasis added:

An incremental dose counter for a metered dose inhaler having a body arranged to retain a canister for movement of the canister relative thereto, the incremental dose counter having a main body, an actuator arranged to be driven and to drive an incremental output member in a count direction in response to canister motion, the actuator being configured to restrict motion of the output member in a direction opposite to the count direction, ***such that the actuator acts as an anti-back drive member when the metered dose inhaler is not being used for inhalation.***

Applicant respectfully submits that Bowman fails to teach or suggest the apparatus of amended claim 23. In particular, Bowman fails to teach or suggest an actuator being configured to restrict motion of the output member in a direction opposite to the count direction, *such that the actuator acts as an anti-back drive member when the metered dose inhaler is not being used for inhalation.* An incremental dose counter with such a configuration may prevent backwards rotation of the output member if an inhaler including the claimed incremental dose counter is accidentally dropped or otherwise unintentionally jostled. The actuator therefore prevents undesirable backwards rotation of the output member, and ensures that the dose counter continues to provide an accurate dosage indication.

Bowman does not teach or suggest the arrangement of the *actuator* when the inhaler is not being used for inhalation. Nor does Bowman consider the problem of backwards rotation if the inhaler is dropped or jolted which may subject the inhaler to greater forces than those during normal use. Bowman discloses a number of means for preventing back-drive of the output

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member, but none of these involve the actuator. For example, Bowman discloses mechanisms for preventing reverse rotation of the axle and ratchet-toothed wheel such as a “*wrap-spring clutch 64*” (column 8, lines 18-30), a “*friction clutch 364*” (column 8, lines 50-54), as well as the features cited by the Examiner as a “means to restrict movement in a direction opposite to the count direction [as] seen at ref. 454 in figure 4 and ref. 654 in figure 6(a).” Office Action page 3. However, the elements the Examiner refers to are not the actuator, as claimed. Instead, the means for preventing back-drive of the output member, as disclosed by Bowman, involve the ratchet-toothed wheel itself or a fixed pawl that is separate and distinct from the actuator and ratchet-toothed wheel. With such mechanisms explicitly disclosed for the purpose of preventing back-rotation, the skilled person would not instead have modified Bowman to use the *actuator* for this purpose.

Bowman only describes the actuator as used for incrementing the dose count and does not consider any secondary use for its actuator. Bowman describes a control surface 371 that prevents interaction between the actuator 341 and the ratchet wheel 360 when the inhaler is not in use. Applicant respectfully submits that there would be no way for the actuator to act as an anti-back drive member when the inhaler is not being used for inhalation as claimed if the actuator only interacts with the ratchet-toothed wheel when a dose is dispensed. Thus, there would have been no motivation for the device of Bowman to be modified in such a way as to arrive at the claimed subject matter. Accordingly, the claimed subject matter is not obvious in view of Bowman.

For at least the foregoing reasons, a *prima facie* case of obviousness has not been established over Bowman with respect to claim 23. Claims 24-28 depend from claim 23, and are therefore also patentable over Bowman, but may be separately patentable for additional reasons as well. Based at least upon the above, Applicant respectfully requests that the Examiner reconsider and withdraw any rejection of claims 23-28.

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CONCLUSION

3. Each and every ground of each rejection in the outstanding office action has been addressed herein. In view of the foregoing, Applicant respectfully submits that the present application is in condition for allowance and such action is respectfully requested. Should the Examiner determine otherwise, Applicant's representatives suggest a telephone interview in order to expedite prosecution of the application.

Respectfully submitted,

Date: October 21, 2021

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